

CLAIMS

What is claimed is:

Claim 1. A biopolymer marker selected from the group consisting of sequence ID (R)AVFPSIVGRPR(H), (D)IPPADLSDQVPDTESETR(I), (R)THLAPYSDELQ(Q), (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or at least one analyte thereof useful in indicating at least one particular disease state.

Claim 2. The biopolymer marker of claim 1 wherein said disease state is predictive of Type II diabetes.

Claim 3. A method for evidencing and categorizing at least one disease state comprising:

obtaining a sample from a patient;

conducting mass spectrometric analysis on said

sample;

evidencing and categorizing at least one biopolymer

marker sequence or analyte thereof isolated from said

sample; and,

comparing said at least one isolated biopolymer

marker sequence or analyte thereof to the biopolymer

marker sequence as set forth in claim 1;

1            wherein correlation of said isolated biopolymer  
2 marker and said biopolymer marker sequence as set forth in  
3 claim 1 evidences and categorizes said at least one  
4 disease state.

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6            Claim 4.    The method of claim 3, wherein said step  
7 of evidencing and categorizing is particularly directed to  
8 biopolymer markers or analytes thereof linked to at least  
9 one risk of disease development of said patient.

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11            Claim 5.    The method of claim 3, wherein said step  
12 of evidencing and categorizing is particularly directed to  
13 biopolymer markers or analytes thereof related to the  
14 existence of a particular disease state.

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16            Claim 6.    The method of claim 3, wherein the sample  
17 is an unfractionated body fluid or a tissue sample.

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20            Claim 7.    The method of claim 3, wherein said sample  
21 is at least one of the group consisting of blood, blood  
22 products, urine, saliva, cerebrospinal fluid, and lymph.

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24            Claim 8.    The method of claim 3, wherein said mass

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1 spectrometric analysis is selected from the group  
2 consisting of Surface Enhanced Laser Desorption Ionization  
3 (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS,  
4 TOF-TOF, and ESI-Q-TOF or an ION-TRAP.

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6 Claim 9. The method of claim 3, wherein said  
7 patient is a human.

8  
9 Claim 10. A diagnostic assay kit for determining  
10 the presence of the biopolymer marker or analyte thereof  
11 of claim 1 comprising:

12 at least one biochemical material which is capable of  
13 specifically binding with a biomolecule which includes at  
14 least said biopolymer marker or analyte thereof, and  
15 means for determining binding between said  
16 biochemical material and said biomolecule;  
17 whereby at least one analysis to determine a presence  
18 of a marker, analyte thereof, or a biochemical material  
19 specific thereto, is carried out on a sample.

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21 Claim 11. The diagnostic assay kit of claim 10,  
22 wherein said biochemical material or biomolecule is  
23 immobilized on a solid support.

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1           Claim 12. The diagnostic assay kit of claim 10  
2 including:

3           at least one labeled biochemical material.  
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5           Claim 13. The diagnostic assay kit of claim 10,  
6 wherein said biochemical material is an antibody.  
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8           Claim 14. The diagnostic assay kit of claim 12,  
9 wherein said labeled biochemical material is an antibody.  
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11           Claim 15. The diagnostic assay kit of claim 10,  
12 wherein the sample is an unfractionated body fluid or a  
13 tissue sample.  
14

15           Claim 16. The diagnostic assay kit of claim 10,  
16 wherein said sample is at least one of the group  
17 consisting of blood, blood products, urine, saliva,  
18 cerebrospinal fluid, and lymph.  
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20           Claim 17. The diagnostic assay kit of claim 10,  
21 wherein said biochemical material is at least one  
22 monoclonal antibody specific therefore.  
23

24           Claim 18. A kit for diagnosing, determining risk-

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1 assessment, and identifying therapeutic avenues related to  
2 a disease state comprising:

3 at least one biochemical material which is capable of  
4 specifically binding with a biomolecule which includes at  
5 least one biopolymer marker selected from the group  
6 consisting of sequence ID (R)AVFPSIVGRPR(H),  
7 (D)IPPADLSDQVPDTESETR(I), (R)THLAPYSDELQ(Q),  
8 (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or at least one analyte  
9 thereof related to said disease state; and

10 means for determining binding between said  
11 biochemical material and said biomolecule;

12 whereby at least one analysis to determine a presence  
13 of a marker, analyte thereof, or a biochemical material  
14 specific thereto, is carried out on a sample.

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16 Claim 19. The kit of claim 18, wherein said  
17 biochemical material or biomolecule is immobilized on a  
18 solid support.

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20 Claim 20. The kit of claim 18 including:  
21 at least one labeled biochemical material.

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23 Claim 21. The kit of claim 18, wherein said  
24 biochemical material is an antibody.

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1           Claim 22.    The kit of claim 20, wherein said labeled  
2 biochemical material is an antibody.

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4           Claim 23.    The kit of claim 18, wherein the sample is  
5 an unfractionated body fluid or a tissue sample.

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7           Claim 24.    The kit of claim 18, wherein said sample  
8 is at least one of the group consisting of blood, blood  
9 products, urine, saliva, cerebrospinal fluid, and lymph.

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11          Claim 25.    The kit of claim 18, wherein said  
12 biochemical material is at least one monoclonal antibody  
13 specific therefore.

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15          Claim 26.    The kit of claim 18, wherein said  
16 diagnosing, determining risk assessment, and identifying  
17 therapeutic avenues is carried out on a single sample.

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19          Claim 27.    The kit of claim 18, wherein said  
20 diagnosing, determining risk assessment, and identifying  
21 therapeutic avenues is carried out on multiple samples  
22 such that at least one analysis is carried out on a first  
23 sample and at least another analysis is carried out on a  
24 second sample.

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1           Claim 28. The kit of claim 27, wherein said first  
2 and second samples are obtained at different time periods.

3  
4           Claim 29. Polyclonal antibodies produced against a  
5 marker sequence ID selected from the group consisting of  
6 sequence ID (R)AVFPSIVGRPR(H), (D)IPPADLSDQVPDTESETR(I),  
7 (R)THLAPYSDELR(Q), (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or  
8 at least one analyte thereof in at least one animal host.

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10          Claim 30. An antibody that specifically binds a  
11 biopolymer including a marker selected from the group  
12 consisting of sequence ID (R)AVFPSIVGRPR(H),  
13 (D)IPPADLSDQVPDTESETR(I), (R)THLAPYSDELR(Q),  
14 (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or at least one analyte  
15 thereof.

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17          Claim 31. The antibody of claim 30 that is a  
18 monoclonal antibody.

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20          Claim 32. The antibody of claim 30 that is a  
21 polyclonal antibody.

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23          Claim 33. A process for identifying therapeutic  
24 avenues related to a disease state comprising:

1           conducting an analysis as provided by the kit of  
2 claim 18; and

3           interacting with a biopolymer selected from the group  
4 consisting of sequence ID (R)AVFPSIVGRPR(H),  
5 (D)IPPADLSDQVPDTESETR(I), (R)THLAPYSDELR(Q),  
6 (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or at least one analyte  
7 thereof;

8           whereby therapeutic avenues are developed.

9  
10           Claim 34.    The process for identifying therapeutic  
11 avenues related to a disease state in accordance with  
12 claim 33, wherein said therapeutic avenues regulate the  
13 presence or absence of the biopolymer selected from the  
14 group consisting of sequence ID (R)AVFPSIVGRPR(H),  
15 (D)IPPADLSDQVPDTESETR(I), (R)THLAPYSDELR(Q),  
16 (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or at least one analyte  
17 thereof.

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19           Claim 35.    The process for identifying therapeutic  
20 avenues related to a disease state in accordance with  
21 claim 33, wherein said therapeutic avenues developed  
22 include at least one avenue selected from a group  
23 consisting of 1)utilization and recognition of said  
24 biopolymer markers, variants or moieties thereof as direct



FOOTNOTES

1 therapeutic modalities, either alone or in conjunction  
2 with an effective amount of a pharmaceutically effective  
3 carrier; 2) validation of therapeutic modalities or disease  
4 preventative agents as a function of biopolymer marker  
5 presence or concentration; 3) treatment or prevention of a  
6 disease state by formation of disease intervention  
7 modalities; 4) use of biopolymer markers or moieties  
8 thereof as a means of elucidating therapeutically viable  
9 agents, 5) instigation of a therapeutic immunological  
10 response; and 6) synthesis of molecular structures related  
11 to said biopolymer markers, moieties or variants thereof  
12 which are constructed and arranged to therapeutically  
13 intervene in said disease state.

14  
15 Claim 36. The process for identifying therapeutic  
16 avenues related to a disease state in accordance with  
17 claim 35, wherein said treatment or prevention of a  
18 disease state by formation of disease intervention  
19 modalities is the formation of biopolymer/ligand  
20 conjugates which intervene at receptor sites to prevent,  
21 delay or reverse a disease process.

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23 Claim 37. The process for identifying therapeutic  
24 avenues related to a disease state in accordance with

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1 claim 35, wherein said means of elucidating  
2 therapeutically viable agents includes use of a  
3 bacteriophage peptide display library or a bacteriophage  
4 antibody library.  
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6 Claim 38. A process for regulating a disease state  
7 by controlling the presence or absence of a biopolymer  
8 selected from the group consisting of sequence ID  
9 (R)AVFPSIVGRPR(H), (D)IPPADLSDQVPDTESETR(I),  
10 (R)THLAPYSDELR(Q), (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or  
11 at least one analyte thereof.  
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